Notice of Allowability	Application No.	Applicant(s)	
	10/025,964	SCHLESSINGER ET AL.	
	Examiner	Art Unit	
	Hemg-der Day	2128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Amendment received 12/30/05*.

2. ☒ The allowed claim(s) is/are *98-150, now renumbered as 1-53*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 3/31/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20060621* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

KAMINI SHAH
SUPERVISORY PATENT EXAMINER

DETAILED ACTION

1. This communication is in response to Applicants' Amendment to Office Action dated October 28, 2005, mailed December 30, 2005, and Applicants' Amendment faxed June 21, 2006.

1-1. Claims 98, 102, 105, 107, 108, 115, 117, 120, 123, 125, 126, 132, 134, 137, 140, 142, 143, and 149 have been amended. Claims 98-150 are pending.

1-2. Claims 98-150 have been examined and allowed.

EXAMINER'S AMENDMENT

2. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

3. Authorization for this Examiner's amendment was given in a telephone interview with Mr. Robert E. Scheid (Reg. No. 42,126) on June 21, 2006.

4. The specification has been amended as follows:

4-1. Replaces paragraph [00094] as follows:

[00094] The set $\hat{s}_i(\omega)$ represents the coefficients of all features other than feature i (i.e., all $s_{i'j'}(\omega)$ for $i' \neq i$ and all j'), and $\hat{x}_i$ represents the set of all x except for x_i. The $\vec{\Theta}^{ij}(\hat{x})$ may be chosen to be a function of the coefficients $\hat{x}_i$ in many different ways. One common choice is using an expansion linear in the coefficients, e.g.,

$$\vec{\Theta}^{ij}(\hat{x}_i) = \vec{\Theta}^{ij}(\vec{\beta}_0^{\,ij} + \sum_{i' \neq i, \text{all } j'}^{I} \vec{\beta}_{i'j'}^{\,ij} x_{i'j'}) \qquad \text{Eq. (25)}$$

and another alternative is using an expansion which depends on some powers of the coefficients, e.g.,

$$\vec{\Theta}^{ij}(\hat{x}_i) = \vec{\Theta}^{ij}(\vec{\gamma}_0^{\,ij} + \sum_{i' \neq i, all\ j'}^{I} \sum_{l=0}^{L} \vec{\gamma}_{i'j'l}^{\,ij} (x_{i'j'})^l) \qquad \text{Eq. (26).}$$

4-2. Replaces paragraph [00096] as follows:

[00096] The likelihood of obtaining all the sample values s_{ij}^k for all the individuals $k = 1...K$, and all the features i, and all the coefficients j for the expression in equation 27 is given by the equation

$$L(\vec{B}, \vec{s}) = \prod_{k=1, i, all\ j}^{K, I} \rho_{ij}(s_{ij}^k, \vec{\Theta}^{ij}(\hat{x}_i)) \qquad \text{Eq. (29),}$$

where $\vec{B}$ is the vector of all coefficients in equation (25) $\vec{B} = \{\vec{\beta}_0^{\,ij} \vec{\beta}_{i'j'}^{\,ij}\}$ or in Eq. (26) $\vec{B} = \{\vec{\gamma}_0^{\,ij}, \vec{\gamma}_{i'j'l}^{\,ij}\}$ and where $\vec{s}$ represents the set of all coefficients obtained by observations on all subjects. The $\vec{B}$ coefficients are determined by maximizing the likelihood in Eq. (29). These coefficients determine the probability distribution function for the coefficients of each term of each feature. Notice that for the form given in Eq. (28), the Fourier expansion can be transformed to the hybrid expansion by incorporating the coefficients of some features into the basis functions.

5. The application has been amended as follows:

5-1. Replace claim 98 as follows:

Claim 98 (currently amended): A computer-implemented method for generating a continuous mathematical model of a feature common to subjects in a subject group, wherein the subjects are biological subjects and the feature is a biological feature, the method comprising:

determining a plurality of sample data sets corresponding to at least one physiological characteristic of the subjects in the subject group;

determining, from the sample data sets, a plurality of values for one or more mathematical parameters corresponding to one or more basis functions for the continuous mathematical model; ~~and~~

determining, from the values for the one or more mathematical parameters, one or more distribution-function parameters for specifying one or more distribution functions for the one or more mathematical parameters, wherein a summation of the one or more basis functions multiplied by sampled values of the one or more distribution functions provides the continuous mathematical model of the feature;

simulating the feature by generating sampled values of the one or more distribution functions by computer;

calculating at least one statistical property of the simulated feature for characterizing the at least one physiological characteristic of the subjects in the subject group; and

saving the at least one statistical property of the simulated feature.

5-2. Replace claim 102 as follows:

Claim 102 (currently amended): A method according to claim 98, wherein determining the values for the one or more mathematical parameters includes:

determining initial values for the one or more mathematical parameters according to an optimization criterion; and

separating the initial values into bins with corresponding bin ranges~~; and~~

~~determining the values for the one or more mathematical parameters by replacing the initial values with the bins~~.

5-3. Replace claim 105 as follows:

Claim 105 (currently amended): A method according to claim 98, further comprising:

~~simulating the feature by generating sampled values of the distribution functions by computer; and~~

displaying the at least one statistical property of the simulated feature.

5-4. Replace claim 107 as follows:

Claim 107 (currently amended): A method according to claim 98, wherein the feature is a first feature selected from a plurality of features[[;]] that includes a second feature, and the method further comprises:

determining, from the sample data sets, a plurality of values for one or more second mathematical parameters corresponding to one or more second basis functions for a continuous mathematical model of the second feature; and

determining, from the values for the one or more second mathematical parameters, one or more second distribution-function parameters, wherein

values for the features other than the ~~first~~ second feature and values for the one or more second distribution-function parameters specify the one or more second distribution functions for the one or more second mathematical parameters, and

a summation of the one or more second basis functions multiplied by sampled values of the one or more second distribution functions provides the continuous mathematical model of the second feature.

5-5. Replace claim 108 as follows:

Claim 108 (currently amended): A method according to claim 107, further comprising:

simulating the ~~first~~ second feature by computer, for given values of the features other than the ~~first~~ second feature, by generating sampled values of the one or more second distribution functions;

calculating at least one statistical property of the simulated second feature for characterizing the at least one physiological characteristic of the subjects in the subject group; and

~~displaying~~ saving the at least one statistical property of the simulated ~~first~~ second feature.

5-6. Replace claim 115 as follows:

Claim 115 (currently amended): A method according to claim 98, wherein ~~the subjects are biological subjects and~~ the feature is selected from the group consisting of blood pressure, cholesterol levels, bone mineral density, patency of a coronary artery, heart electrical potentials, contractility of myocardium, cardiac output, visual acuity, serum potassium level, observations for a rash, diameter of a coronary artery, and cancer spread measurements ~~a biological feature~~.

5-7. Replace claim 117 as follows:

Claim 117 (currently amended): An apparatus for generating a continuous mathematical model of a feature common to subjects in a subject group, wherein the subjects are biological subjects and the feature is a biological feature, the apparatus comprising a computer for executing computer instructions, wherein the computer includes computer instructions for:

determining a plurality of sample data sets corresponding to at least one physiological characteristic of the subjects in the subject group;

determining, from the sample data sets, a plurality of values for one or more mathematical parameters corresponding to one or more basis functions for the continuous mathematical model; ~~and~~

determining, from the values for the one or more mathematical parameters, one or more distribution-function parameters for specifying one or more distribution functions for the one or more mathematical parameters, wherein a summation of the one or more basis functions multiplied by sampled values of the one or more distribution functions provides the continuous mathematical model of the feature;

simulating the feature by generating sampled values of the one or more distribution functions by computer;

calculating at least one statistical property of the simulated feature for characterizing the at least one physiological characteristic of the subjects in the subject group; and

saving the at least one statistical property of the simulated feature.

5-8. Replace claim 120 as follows:

Claim 120 (currently amended): An apparatus according to claim 117, wherein determining the values for the one or more mathematical parameters includes:

determining initial values for the one or more mathematical parameters according to an optimization criterion; and

separating the initial values into bins with corresponding bin ranges~~; and~~

~~determining the values for the one or more mathematical parameters by replacing the initial values with the bins~~.

5-9. Replace claim 123 as follows:

Claim 123 (currently amended): An apparatus according to claim 117, wherein the computer further includes computer instructions for:

~~simulating the feature by generating sampled values of the distribution functions; and~~

displaying the at least one statistical property of the simulated feature.

5-10. Replace claim 125 as follows:

Claim 125 (currently amended): An apparatus according to claim 117, wherein the feature is a first feature selected from a plurality of features[[;]] that includes a second feature, and the computer further includes computer instructions for:

determining, from the sample data sets, a plurality of values for one or more second mathematical parameters corresponding to one or more second basis functions for a continuous mathematical model of the second feature; and

determining, from the values for the one or more second mathematical parameters, one or more second distribution-function parameters, wherein

values for the features other than the ~~first~~ second feature and values for the one or more second distribution-function parameters specify the one or more second distribution functions for the one or more second mathematical parameters, and

a summation of the one or more second basis functions multiplied by sampled values of the one or more second distribution functions provides the continuous mathematical model of the second feature.

5-11. Replace claim 126 as follows:

Claim 126 (currently amended): An apparatus according to claim 125, wherein the computer further includes computer instructions for:

simulating the ~~first~~ second feature by computer, for given values of the features other than the ~~first~~ second feature, by generating sampled values of the one or more second distribution functions;

calculating at least one statistical property of the simulated second feature for characterizing the at least one physiological characteristic of the subjects in the subject group; and

~~displaying~~ saving the at least one statistical property of the simulated ~~first~~ second feature.

5-12. Replace claim 132 as follows:

Claim 132 (currently amended): An apparatus according to claim 117, wherein ~~the subjects are biological subjects and~~ the feature is selected from the group consisting of blood pressure, cholesterol levels, bone mineral density, patency of a coronary artery, heart electrical potentials, contractility of myocardium, cardiac output, visual acuity, serum potassium level, observations for a rash, diameter of a coronary artery, and cancer spread measurements ~~a biological feature~~.

5-13. Replace claim 134 as follows:

Claim 134 (currently amended): A computer-readable medium that stores a computer program for generating a continuous mathematical model of a feature common to subjects in a subject group, wherein the subjects are biological subjects and the feature is a biological feature, the computer program comprising instructions for:

determining a plurality of sample data sets corresponding to at least one physiological characteristic of the subjects in the subject group;

determining, from the sample data sets, a plurality of values for one or more mathematical parameters corresponding to one or more basis functions for the continuous mathematical model; ~~and~~

determining, from the values for the one or more mathematical parameters, one or more distribution-function parameters for specifying one or more distribution functions for the one or more mathematical parameters, wherein a summation of the one or more basis functions multiplied by sampled values of the one or more distribution functions provides the continuous mathematical model of the feature;

simulating the feature by generating sampled values of the one or more distribution functions by computer;

calculating at least one statistical property of the simulated feature for characterizing the at least one physiological characteristic of the subjects in the subject group; and

saving the at least one statistical property of the simulated feature.

5-14. Replace claim 137 as follows:

Claim 137 (currently amended): A computer-readable medium according to claim 134, wherein determining the values for the one or more mathematical parameters includes:

determining initial values for the one or more mathematical parameters according to an optimization criterion; and

separating the initial values into bins with corresponding bin ranges~~; and~~

~~determining the values for the one or more mathematical parameters by replacing the initial values with the bins~~.

5-15. Replace claim 140 as follows:

Claim 140 (currently amended): A computer-readable medium according to claim 134, wherein the computer program further comprises instructions for:

~~simulating the feature by generating sampled values of the distribution functions; and~~

displaying the at least one statistical property of the simulated feature.

5-16. Replace claim 142 as follows:

Claim 142 (currently amended): A computer-readable medium according to claim 134, wherein the feature is a first feature selected from a plurality of features[[;]] that includes a second feature, and the computer program further comprises instructions for:

determining, from the sample data sets, a plurality of values for one or more second mathematical parameters corresponding to one or more second basis functions for a continuous mathematical model of the second feature; and

determining, from the values for the one or more second mathematical parameters, one or more second distribution-function parameters, wherein

values for the features other than the ~~first~~ second feature and values for the one or more second distribution-function parameters specify the one or more second distribution functions for the one or more second mathematical parameters, and

a summation of the one or more second basis functions multiplied by sampled values of the one or more second distribution functions provides the continuous mathematical model of the second feature.

5-17. Replace claim 143 as follows:

Claim 143 (currently amended): A computer-readable medium according to claim 142, wherein the computer program further comprises instructions for:

simulating the ~~first~~ second feature by computer, for given values of the features other than the ~~first~~ second feature, by generating sampled values of the one or more second distribution functions;

calculating at least one statistical property of the simulated second feature for characterizing the at least one physiological characteristic of the subjects in the subject group; and

~~displaying~~ saving the at least one statistical property of the simulated ~~first~~ second feature.

5-18. Replace claim 149 as follows:

Claim 149 (currently amended): A computer-readable medium according to claim 134, wherein ~~the subjects are biological subjects and~~ the feature is selected from the group consisting of blood pressure, cholesterol levels, bone mineral density, patency of a coronary artery, heart electrical potentials, contractility of myocardium, cardiac output, visual acuity, serum potassium level, observations for a rash, diameter of a coronary artery, and cancer spread measurements ~~a biological feature~~.

Reasons for Allowance

6. The following is an Examiner's statement of reasons for allowance:

6-1. The closest prior art of record discloses:

(1) A model reduction method using K-L expansion (Newman, "Model Reduction via the Karhunen-Loeve Expansion Part I: An Exposition").

(2) A continuous, stochastic microsimulation model of type 2 diabetes (Brown et al., "The Global Diabetes Model: User Friendly Version 3.0").

(3) A mathematical model of a joint (Defranoux et al., U.S. Patent 6,862,561).

6-2. The prior art does not expressly teach or render obvious the invention as recited in independent claims 98, 117, and 134.

Generating a continuous, stochastic mathematical model of biological subjects and features as well as K-L expansion are obvious as disclosed in the prior art of record. However, determining distribution function parameters from the sample data sets via the determined values for the mathematical parameters and the use of the basis functions multiplied by sampled values to provide continuous model for simulation biological feature in a biological subject group, in the context of the claims, was not uncovered in the prior art teachings.

The limitations directed to the specific environment of biological subjects and biological feature as recited in preambles of claims 98, 117, and 134 are accorded patentable weight as they recite and provide limitations are required for completeness of the claims to provide practical applications. The courts have held that "[A] claim preamble has the import that the claim as a whole suggests for it." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). Further, "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." Pitney Bowes, Inc. v. Hewlett-Packard

Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Moreover, as the courts have held that "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) and "The identical invention must be shown in as complete detail as is contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Nor was a reference uncovered that would have provided a basis of evidence for asserting a motivation that one of ordinary skill in the art at the time the invention was made, knowing of this specific environment, would have applied the K-L expansion and modified a mathematical biological model to simulate biological feature and calculate the statistical property of the simulated biological feature as recited in the context of the independent claims.

Dependent claims are allowed as they depend upon allowable independent claims.

7. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Herng-der Day whose telephone number is (571) 272-3777. The Examiner can normally be reached on 9:00 - 17:30.

Any inquiry of a general nature or relating to the status of this application should be directed to the TC 2100 Group receptionist: (571) 272-2100.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Kamini S. Shah can be reached on (571) 272-2279. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Herng-der Day
June 21, 2006 H.D.

KAMINI SHAH
SUPERVISORY PATENT EXAMINER